

## **REMARKS**

In the Office Action mailed February 5, 2007, claims 61 and 98-102 were rejected under 35 U.S.C. § 101 as being directed toward non-statutory subject matter; claims 50-107 and 142-149 were rejected 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,094,598 to Elsberry et al.; claim 60 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Elsberry et al. in view of U.S. Patent No. 6,731,964 to Shenoy et al.; and claims 86, 88 and 108 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Elsberry et al. in view of U.S. Patent Publication No. 2003/0139778 to Fischell et al. Non-elected claims 1-49 and 109-141 were withdrawn.

By this amendment, Applicants have cancelled claim 61 without prejudice or disclaimer of the subject matter thereof. Accordingly, the 35 U.S.C. § 101 rejection with respect to claim 61 is moot and should be withdrawn. Applicants have also amended claims 142 and 147, to more appropriately define Applicants' invention. No new matter has been added by this reply.

Applicants respectfully traverse the 35 U.S.C. § 101 rejection with respect to claims 98-102 as being directed toward non-statutory subject matter. In the Office Action, the Examiner asserts that claims 98-102 intend "to claim a body part, brain, tumor, CNS system, body organ, and bone marrow..." (See Office Action at page 2). Applicants respectfully disagree with the Examiner's assertion.

Claims 98-102 each depend from claim 50. Claim 50 recites a system for treating a body including, among other things, "a sensor configured to be proximate to a first part of the body." Claims 98-102 each identify a particular body part associated with "a first part of the body" recited in claim 50. Contrary to the Examiner's assertion,

however, claims 98-102 do not claim a portion of the body, but rather describe a configuration of a sensor, which is part of the statutory classes of subject matter under 35 U.S.C. § 101. Accordingly, the 35 U.S.C. § 101 rejection with respect to claims 98-102 is improper and should be withdrawn.

Applicants respectfully traverse the 35 U.S.C. § 102(b) rejection of claims 50-107 and 142-149 as being anticipated by Elsberry et al. for at least the reason that Elsberry et al. fails to disclose every claim element. For example, independent claim 50, from which claims 51-107 ultimately depend, recites a system for treating a body including, among other things, a first processor connected to a sensor for processing detected electrical signals to generate a first control signal; a device configured to receive the first control signal and be controlled by the first control signal; and a second processor configured to generate a second control signal based on a monitored parameter of the device and to provide information relating to delivery of an agent to the body based on the second control signal. Elsberry et al. fails to disclose, at least, a second processor configured to generate a second control signal based on a monitored parameter of the device.

In the Office Action, the Examiner asserts that sensor (130), analog-to-digital converter (140), device (10), and microprocessor (100) of the Elsberry et al. system respectively correspond to the claimed sensor, first processor, device, and second processor. The Examiner further asserts that the microprocessor (100) of Elsberry et al. is “configured to generate a second signal based on a monitored parameter of the device to provide information relating to delivery of an agent.” (See Office Action at

page 3.) Applicants respectfully disagree with the Examiner's characterization of Elsberry et al.

Elsberry et al. discloses that sensor (130) monitors nerve cell activity and provides the monitored data to digital converter (140), which converts the monitored data to a digital output signal. Based on the output signal of digital converter (140), microprocessor (100) of drug delivery device (10) selects from a drug dose and time interval for delivering the drug to a patient. (See Elsberry et al. col. 5, lines 1-65 and Fig. 3.) Microprocessor (100), however, does not generate a control signal based on a *monitored parameter of device (10)*, as recited in Applicants' independent claim 50. Instead, microprocessor (100) bases its signal on the output of converter (140), which receives monitored data from sensor (130).

The Examiner does not cite any disclosure of Elserry et al. for a teaching that microprocessor (100) bases its signal on a monitored parameter of device (10). The Examiner only alleges that Elsberry et al. "is capable of using the control signal information to store data relating to agent delivery and control delivery based [on] information for controlling in response to a sensed condition ([Elsberry et al. at] col. 5, In 35-70)." However, the cited paragraphs relied on by the Examiner refer to the sensed condition of Elsberry et al. as data collected by sensor (130), which only relates to cell activity and does not include parameters of device (10). (See Elsberry et al. at col. 4, line 28 - col. 5, line 23.)

Thus, no disclosure in Elsberry et al. teaches or suggests that microprocessor (100) of Elsberry et al. generates a control signal based on a *monitored parameter of device (10)*.

Amended independent claim 142, from which claims 143-149 ultimately depend, recites a combination of elements including, among other things, a first processor connected to the sensor for processing the detected electrical signals to generate a first control signal; a device configured to receive the first control signal and be controlled by the first control signal; and a second processor configured to generate a second control signal based on a measured parameter of at least one of the detected electrical signals and the first control signal, the second processor configured to provide information relating to delivery of an agent to the body to a second device based on the second control signal. Elsberry et al. fails to disclose, at least, a second processor configured to provide information relating to delivery of an agent to the body to a second device based on the second control signal.

As noted above, the Elserry et al. microprocessor (100) of drug delivery device (10) selects from a drug dose and time interval for delivering the drug to a patient based on an output signal of analog-to-digital converter (140), which receives monitored data from sensor (130). Microprocessor (100), however, does not provide information relating to delivery of an agent to the body *to a second device*, as required by Applicants' amended independent claim 142.

Because Elsberry et al. fails to disclose or suggest every claim element of independent claims 50 and 142, or claims 51-107 and 143-149 that depend therefrom, the 35 U.S.C. § 102(b) rejection of these claims is improper and should be withdrawn.

Applicants also note that that the Office Action groups a number of claims together in a common rejection, without specifically addressing certain features contained in one or more of the rejected claims. For example, claim 65, which depends

from independent claim 50, is directed toward an embodiment of claim 50, "wherein the second control signal is used to display information for delivery of an agent." Similarly, claim 84, which depends from independent claim 50, is directed toward an embodiment of claim 50, "wherein the second processor is configured to transmit information relating the second control signal to a practitioner." The Office Action fails to cite any references that disclose these features. In fact, the Office Action has failed to address these claim elements altogether. Accordingly, Applicants respectfully submit that dependent claims 51-107 and 143-149 are in condition for allowance for, at least, their dependence from independent claims 50 and 142 and further in view of their additional recitations.

Applicants respectfully traverse the 35 U.S.C. § 103(a) rejections of claims 60, 86, 88, and 108. Each of these claims depends from independent claim 50. The secondary applied references do not remedy the deficiencies of Elsberry et al. described above. Accordingly, the 35 U.S.C. § 103(a) rejection of these claims is improper and should be withdrawn.

In view of the foregoing amendments and remarks, Applicants respectfully request reconsideration and reexamination of this application and the timely allowance of the pending claims.

The Office Action contains a number of characterizations and assertions regarding the claims and the cited art with which Applicants do not necessarily agree. Unless expressly noted otherwise, Applicants decline to subscribe to any statement or characterization in the Office Action.


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Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,  
GARRETT & DUNNER, L.L.P.

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By:   
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Brad C. Rametta  
Reg. No. 54,387